510(k) Summary

OCT 2 8 2010

Administrative Information

Manufacturer Name: Keystone Dental, Inc.
144 Middlesex Turnpike
Burlington, MA 01803
Telephone: (781) 328-3300
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Official Contact: John A. Capone, RAC

Date Prepared: October 27, 2010

Device Name and Classification

Trade/Proprietary Name: Genesis Implant System
Common Name: Dental Implants and Abutments
Classification Information: Endosseous Dental Implant
(21 CFR 872.3640), Class II
Endosseous Dental Implant Abutment
(21 CFR 872.3630), Class II
Product Codes DZE, NHA

Device Classification Panel

The Classification Panel for these devices is the Dental Products Panel. Premarket Notifications are reviewed by FDA's Dental Devices Branch.

Legally Marketed Devices to Which Equivalence is Claimed (Predicate Devices)

Device Name	Manufacturer	510(k) Number(s)
PrimaConnex™ Internal Connection Implant System	Keystone Dental	K051614
Straumann® Dental Implant System	Straumann	K053088, K061176
NanoTite™ Dental Implants	Biomet 3i	K062432
TiUnite® NobelActive™ Implants	Nobel Biocare	K050705, K071370

Device Description

The Genesis Implant System includes implants, abutments, and associated surgical, restorative and dental laboratory components. Genesis implants are surgically inserted into the upper and/or lower jawbone and serve as a replacement tooth root, which provides a stable foundation for restorations.

Genesis implants are manufactured from Grade 4 titanium, have a tapered or straight cylindrical design with an internal indexing connection, and are available in various platform diameters and lengths (see table below).

Implant Type	Implant Diameter	Implant Lengths
Straight Implant	3.8mm	8.5, 10, 11.5, 13, 14.5, 16 & 18mm
	4.5mm	8.5, 10, 11.5, 13, 14.5, 16 & 18mm
Tapered Implant	3.8mm	8.5, 10, 11.5, 13, 14.5, 16 & 18mm
	4.5mm	8.5, 10, 11.5, 13, 14.5, 16 & 18mm
	5.5mm	8.5, 10, 11.5, 13, 14.5 & 16mm
	6.5mm	8.5, 10, 11.5 & 13mm

The implants have a macro-, micro- and nano-topography and are treated with the BioSpark™ process, which results in a hydrophilic surface enriched with calcium and phosphorous ions. The implant collar is micro-roughened and treated with the AnaTite™ process, which results in a pink color for enhanced esthetics.

The majority of Genesis abutments are manufactured from Grade 5 titanium and are treated with the AnaTite process. Other Genesis abutments are made from Grade 5 titanium/plastic or gold alloy/plastic. Abutments intended for fixed restorations utilize a Grade 5 titanium screw for attachment to the implant. Genesis abutments and associated restorative components are manufactured in a variety of sizes and configurations to be compatible with the implant platforms (see table below).

Abutment Type	Abutment Material	Abutment Angulations
Healing Abutment	Grade 5 titanium	N/A
Temporary Abutment	Plastic (PMMA)	N/A
Ti Temporary Abutment	Grade 5 titanium	N/A
Esthetic Contour Ti Abutment	Grade 5 titanium	Straight and 15°
UCLA Gold/Plastic Sleeve	Gold Alloy/ Plastic (POM)	N/A
SureConnect Abutment	Grade 5 titanium	N/A
Locator Abutment	Grade 5 titanium	N/A
Snap Abutment	Grade 5 titanium	N/A

Indications for Use

The Genesis Implant System is intended for use in single-stage or two-stage surgical procedures in all types of bone in partially or fully edentulous mandibles and maxillae. The Genesis Implant System supports single or multiple-unit restorations to re-establish patient chewing function and esthetics. Genesis implants are intended for placement following natural tooth loss or for immediate placement into an extraction socket. Immediate function may be achieved when good primary stability is established and appropriate occlusal loading is applied.

Summary of Technological Characteristics

Predicate devices for the Genesis Implant System were selected based on similar intended use and technological characteristics. All devices are intended for replacing missing teeth and supporting single or multiple-unit restorations in the mandible and/or maxilla. Genesis implants are similar in design and materials to the predicates in that all are threaded, root-form implants.

Genesis, SLActive and TiUnite implants are all constructed of biocompatible Grade 4 titanium and are sterilized using gamma radiation. Genesis implants are macro- and micro-roughened as are PrimaConnex, SLActive and TiUnite implants. Genesis implants are further treated with the BioSpark process, which results in a nano-rough topography. NanoTite implants are similar in this regard, as they also feature a nano-rough surface. In addition to the nano-topography, the BioSpark process produces a hydrophilic surface. These surface characteristics are also found on SLActive implants. The BioSpark surface incorporates calcium and phosphorus ions to create an enriched surface, a characteristic shared by NanoTite and TiUnite implants.

Genesis abutments are made from biocompatible materials used in the predicate PrimaConnex, SLActive, NanoTite and TiUnite abutments, including Grade 5 titanium, gold alloy and plastic. The Genesis system has the same implant/abutment TiLobe™ internal connection as the PrimaConnex system. Genesis titanium alloy abutments and implant collars receive the AnaTite surface treatment, which produces a pink-colored surface intended to resemble the appearance of gingival tissue. The color is produced by anodization, a common process for treating titanium, which is also used for components of the Straumann and PrimaConnex implant systems.

Summary of Non-Clinical Testing

The performance of the Genesis Implant System has been demonstrated through non-clinical testing and published literature. The following is a summary of the relevant *in vivo* and *in vitro* studies and bench testing.

Genesis implants with angled abutments were fatigue tested in accordance with ISO 14801 and the FDA's Special Controls Guidance on root-form endosseous dental implants and abutments. Genesis instruments, implant threads, and implantation procedures have been designed to optimize insertion torque in order to limit the pressure applied to bone while ensuring good primary stability. In a bench study using simulated bone material, moderate insertion torque was shown when Genesis implants were placed utilizing appropriate surgical instrumentation.

The AnaTite treatment produces a pink coloration on the surface of the Genesis implant collar and abutments. An *in vivo* study has shown that pink coloration most closely resembles natural gingival tissue.

The BioSpark treatment produces chemical and physical implant surface characteristics that promote osseointegration. These characteristics have been evaluated by various methods. Contact angle (wettability) testing has shown the Genesis implant surface to be hydrophilic. Energy dispersive spectroscopy and sputter mass spectroscopy have confirmed the presence of calcium and phosphorus ions on BioSpark treated surfaces. Mineralization potential of the BioSpark surface has been reported in published literature. Surface roughness at the macro-, micro-, and nano-level has been demonstrated through scanning electron microscopy. These combined characteristics of the BioSpark surface facilitate faster osseointegration, as demonstrated by significant bone-to-implant-contact (BIC) in the cortical bone of sheep* at 4 weeks compared to machined or blasted titanium, and as demonstrated by *in vitro* studies, which yielded the following individual results:

- Significant increase in cellular metabolic activity over 1 to 7 days in simulated body fluid on cp-Ti disks treated with BioSpark when compared to machined titanium
- Significant increase in osteoblast proliferation over 1 to 3 days on cp-Ti disks treated with BioSpark when compared to machined or acid etched titanium
- Early fibronectin absorption and enhanced adhesion, proliferation, and differentiation of osteoblasts at 24, 48 and 72 hours on cp-Ti disks treated with BioSpark when compared to other anodic spark deposition (ASD) surfaces

*Results in animal studies are not necessarily predictive of human clinical results.

Conclusion

The Genesis Implant System utilizes the same materials and exhibits similar mechanical properties and surface characteristics as the predicate implant systems. The information provided in this 510(k) premarket notification supports the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. John A. Capone
Director, Regulatory Affairs and Quality Assurance
Keystone Dental, Inc.
144 Middlesex Turnpike
Burlington, Massachusetts 01803

OCT 28 2010

Re: K101545
Trade/Device Name: Genesis Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: October 22, 2010
Received: October 25, 2010

Dear Mr. Capone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

OCT 2 8 2010

510(k) Number (if known): K101545

Device Name: Genesis Implant System

Indications for Use:

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101545